IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
COLUMBUS DIVISION

IN RE MENTOR CORP. OBTAPE TRANSOBTURATOR SLING PRODUCTS LIABILITY LITIGATION	§ § § § §	MDL Case No. 2004 Individual Case No. 4:11-cv-5065 (Morey, Irene)

PLAINTIFF'S RESPONSE IN OPPOSITION TO MENTOR'S MOTION *IN LIMINE* NO. 6: MOTION TO EXCLUDE EVIDENCE AND ARGUMENT REGARDING MENTOR'S CONDUCT POST-DATING PLAINTIFF'S IMPLANT SURGERY

TO THE HONORABLE UNITED STATES DISTRICT JUDGE:

COMES NOW, the Plaintiff, and files this Response in Opposition to Mentor's Motion in Limine No. 6, and shows the following:

Statement of Factual and Procedural Background

In its Motion in Limine No. 6, Mentor seeks to exclude evidence "regarding Mentor's conduct and awareness post-dating Plaintiff's implant surgery." Mentor's motion should be denied because this issue has already been decided in Plaintiff's favor, which is now the law of the case. Further, post-implant evidence is relevant and admissible as to Plaintiff's cause of action, as well as punitive damages.

Argument and Citation of Authority

A. The Issues Herein Have Already Been Ruled Upon In Plaintiff's Favor

To the extent that Mentor's Motion in Limine No. 6 overlaps with its previous Motion in Limine No. 10 filed by Mentor in 2010, this Court's previous rulings are the law of the case and therefore control. *Oladeinde v. City of Birmingham*, 230 F.3d 1275, 1288 (11th Cir. 2000).

In 2010, this Court ruled, after conducting independent research, that the admission of

evidence of subsequent incidents should be decided under the Federal Rules of Evidence. (Exh. A - Dkt. 302, p. 2). This Court relied on *Heath v. Suzuki Motor Corp.*, to find that the Federal Rules of Evidence, not Georgia law, govern the admissibility of similar transaction evidence in products liability action where federal jurisdiction is predicated upon diversity of citizenship. (Exh. A - Dkt. 302, p 2); *see Heath*, 126 F.3d 1391, 1396 (11th Cir. 1997).

On the issue of the admission of subsequent incidents of ObTape complications, this Court conclusively stated, "[t]he Court finds that subsequent incidents of ObTape complications that are substantially similar to those experienced by Plaintiffs may be admissible at trial." (Exh. A - p. 1). Under binding Eleventh Circuit precedent, "[E]vidence of similar occurrences may be offered to show a defendant's notice of a particular defect or danger, the magnitude of the defect or danger involved, the defendant's ability to correct a known defect, the lack of safety for intended uses, the strength of a product, the standard of care, and causation." (Exh. A p. 3 citing *Hessen v. Jaguar Cars*, 915 F.2d 641, 650 (11th Cir. 1990)) (emphasis added by this Court).

The Court has already rejected Defendant's argument. The admissibility of this critical evidence has already been established. With regard to the present Motion, Plaintiff simply requests the same ruling be applied to the current cases set for trial.

B. "Post-implant" Evidence is Relevant and Admissible as to Plaintiffs' claims

Although federal law applies here as to whether subsequent incidents are admissible at trial and are relevant on the issue of causation, as this Court has previously established, subsequent incidents would likely also be admissible under Minnesota law. Plaintiff has alleged a products liability claim against Mentor under a theory of negligence for designing, manufacturing, testing, marketing, labeling, packaging, selling and/or distributing the ObTape vaginal sling that was defective and unreasonably hazardous. (Am. Compl. ¶¶ 23-24). Under Minnesota law, in order to establish a products liability claim based upon a defective design, a plaintiff must show that: 1) the defendant's product was in a defective condition unreasonably

dangerous for its intended use; 2) the defect existed when the product left the defendant's control; and 3) the defect was the proximate cause of the injury sustained. *Bilotta v. Kelley Co.*, 346 N.W.2d 616, 623 n. 3 (Minn.1984); *Marcon v. Kmart Corp.*, 573 N.W.2d 728, 731 (Minn.Ct.App.1998), *review denied*, Apr. 14, 1998. In design defect cases, Minnesota courts have fused a negligence theory into a traditional strict liability theory to determine whether a product was defective. *See Johnson v. John Deere Co.*, 935 F.2d 151, 155 (8th Cir.1991); *Westbrock v. Marshalltown Mfg. Co.*, 473 N.W.2d 352, 356 (Minn.Ct.App.1991). Accordingly, a product is in a defective condition unreasonably dangerous for its intended use if the manufacturer:

> fails to exercise that degree of care in his plan or design so as to avoid any unreasonable risk of harm to anyone who is likely to be exposed to the danger when the product is used in the manner for which the product was intended, as well as an unintended yet reasonably foreseeable use.

Bilotta, 346 N.W.2d at 621.

The issue of defective design is at the heart of this litigation. Whether the design of the ObTape is defective and dangerous and whether the ObTape's defective design causes the sort of injuries suffered by this Plaintiff[1] are not inquiries that are "fixed" at any given point in time. Thus, "pre-implant" and "post-implant" evidence bear equally on both of these issues, including any evidence that bears on defect, to wit: (A) *Evidence of scientific testing or analysis, at any time*. For instance, if an engineer performed an evaluation of the product, whether one day after sale or one day before trial; (B) *Evidence of other complications/failures involving the product*. This type of evidence is essentially the results of "testing" in the field, particularly when no pre-sale safety testing was done. Evidence of other similar incidents is relevant to whether the

[1] In this case, nearly every expert who has testified – for both parties – as to the issues of defective design and causation has based his or her opinion on published data that post-dates this particular plaintiff's implantation (including numerous articles and studies that Mentor contends supports its defect/causation arguments).

product is dangerous.[2] If the law were otherwise, then any test conducted by either party after the occurrence of the incident in litigation would be inadmissible, as would any expert opinion based on any after-the-fact test or study performed expressly for purposes of determining whether or not a product was defective. That is not the law.

Minnesota products liability law recognizes a continuing duty to warn of dangers associated with using a product. *Hodder v. Goodyear Tire & Rubber Co.*, 426 N.W.2d 826, 833 (Minn. 1988). The manufacturer's duty to inspect and test its products is subpart of duties to design a product non-negligently, manufacture a product non-negligently, and provide adequate warnings of dangers associated with its use. *Kociemba v. G.D. Searle & Co.*, 707 F.Supp. 1517, 1528 (D.Minn.1989) (The purpose of the manufacturer's duty to test is to discover any associated defects or dangers); *see also Lillebo v. Zimmer, Inc.*, 2005 WL 388598, *8 (D.Minn.2005) ("The manufacturer has a duty to adequately test its product and design as part of determining whether the risks associated with the product are outweighed by the benefits").

If the manufacturer fails to test its product for safety, as Mentor failed to do in this case,[3] it cannot validly assert any lack of "actual knowledge" when the dangers and defects that such testing would have revealed manifest themselves. Likewise, it cannot preclude evidence of those foreseeable dangers. The jury should be allowed to consider not only what was known to Mentor, but also what the company would have known had it done appropriate testing (or *any* testing) to determine the safety of this radical new mesh design before releasing this product on

[2] While laboratory testing and scientific analysis are useful, they cannot be the last or only word – especially where, as here, the manufacturer performs no testing or analysis before launching the product. The "real world" clinical experience is, subject to expert analysis and discussion, relevant to design defect and to causation.

[3] Plaintiff will show that Mentor did *nothing* to test the implantation biocompatibility of the ObTape before releasing the product to be implanted in women's bodies in this country.

the market.[4] Excluding post-implant evidence under the facts of this case would only serve to reward Mentor's negligent failure to test or otherwise to determine the safety of its product before unleashing it on the public. Post-implant evidence should be admitted for purposes of Plaintiffs' claims.

(C) Plaintiffs Should be Allowed to Present Post-Implant Warnings to the Jury to Decide the Post-Implant Duty to Warn

Plaintiff's claims are based upon well-established principles of Minnesota law that a manufacturer has a continuing duty to warn individuals about dangers that the company becomes aware of, even if that knowledge is acquired after the product is sold (or, in this case, implanted). *Kociemba v. G.D. Searle & Co.*, 707 F.Supp. 1517, 1528 (D. Minn. 1989) (citing *Hodder v. Goodyear Tire & Rubber Co.*, 426 N.W.2d 826, 833 (Minn. 1988)). Questions of a warning's adequacy, breach and causation are usually jury questions. *Balder v. Haley*, 399 N.W.2d 77, 81 (Minn.1987).

Mentor alleges that Plaintiff has not identified any post-implant warnings that could be causally connected to her injuries. Without proffering all of Plaintiff's trial evidence here, the Plaintiff will present both pre-implant and post-implant evidence that Mentor received notice that upon any infection or erosion experienced with ObTape, the *entire* tape should be removed rather than just removing the eroded or infected portion of the tape, which is how such complications were treated with other competing tapes. (*See* ObTape/French Confidential 00300 – 11/05/04 - Exh. B) ("When erosion occurred with ObTape, it is important to remove the tape to

[4] For example, Plaintiff will show that AFSSAPS informed the company in February 2006 that it had conducted an inquiry to describe the rate of occurrence of all post-operative complications related to vaginal tapes, and that ObTape was shown to have a rate of erosion, cellulitis and abscess over 10% - by far the highest among all products. While this information post-dates this Plaintiff's implantation, it is nonetheless reflective of what Mentor would have known had it conducted the sort of clinical study that AFSSAPS conducted. It certainly reflects the severity and frequency of the danger of the product, and is also relevant to the issues punitive damages and the company's continuing duty to warn.

minimize the risk of infection, and not simply cover it as usually done with other tapes.") and (Mentor/Obtape Confidential 026400 – 3/05/04 - Exh. C) ("If there is an infection (pus), remove the whole tape….")). It will further be proven in this case that Mentor never provided this critical information to the Plaintiff's physicians, and as a result, Plaintiff underwent surgery in which only portions of the tape was removed, and consequently she experienced continuing complications.[5] The decision not to inform doctors of this information – even in the face of two separate documents indicating that this is the way ObTape complications should be treated – was made by Mentor's marketing manager for women's health products, Delia Cook, the employee responsible for marketing and promoting ObTape. (Cook depo. at 105:19-110:16 and 172:9-176:16 (Exh. D)). In fact, instead of warning doctors about the need to remove the entire tape in the event of complication, Mentor actually commissioned an instructional video (by Mentor expert Dr. Carl Klutke) teaching doctors that in the event of infection, remove the infected portion or segment of the sling (which is exactly what the Plaintiff's doctor did, and for which she is now being accused of malpractice).

The evidence will further show that Mentor failed to warn doctors or ObTape recipients of serious, late onset infections that were experienced with the ObTape, which were different from the complications that had been seen with other suburethral slings (generally early-onset, localized infections treatable with antibiotics). The company knew these problems were particularly problematic because the patient may not relate her complications to her ObTape and thus may not seek appropriate treatment. For example, a November 5, 2004 internal memo relating to the company's experience with ObTape in France stated that "[t]here is a suspicion

[5] Plaintiff's continuing duty to warn theory squarely applies under the facts of this case. Mentor alleges that, among other acts of malpractice, the Plaintiff's doctors negligently failed to timely remove the entire sling upon the Plaintiff's initial presentation with complications. Particularly in light of Mentor's asserted defense to these cases, the jury should be allowed to consider all the relevant facts bearing on Mentor's continuing duty to warn.

concerning ObTape, and it seems that ObTape is less tolerant when there is erosion and it leads to a more important rate of infections, with some serious cases." (ObTape/French Confidential 00300 - Exh. B). The August 2005 Gremaud/Ortuno Report discusses 14 cases of "severe infection (abscess or cellulitis)" related to ObTape and observed that the number of severe infections "bec[a]me more pronounced with time." (Mentor/Obtape Confidential _048095 - Exh. E)) Most troubling, the Report states that the time of onset was as late as 24 months, and notes that "[**t**]**he late onset time is related to the development of severe infections: the patient no longer makes the connection between symptoms and the tape, lets the situation drag on and/or gets treated by a practitioner who is unaware that there is a tape and thus does not apply the appropriate treatment (removal of the tape)**." (*Id.*). Mentor plainly recognized based on the worldwide clinical experience with the ObTape that its product behaved differently *in vivo* and responded differently to standard treatment than other products, and caused complications different from those related to other products, and it knew that doctors and patients may not appreciate the complications or how to properly treat them. Mentor had a duty under Minnesota law to warn doctors and patients about these risks even after Plaintiff was implanted so that she and her doctors would be cognizant of and vigilant for such potential complications, and so that the doctors would know what to do in the event a patient presented with such a problem. Plaintiff should be allowed to present evidence bearing on such claim.

(**D) Subsequent evidence is relevant and admissible as to punitive damages.**

The focus of a punitive damages award in a product action in Minnesota is the defendant's conduct, not the plaintiff's injury. *See Jensen v. Walsh*, 623 N.W.2d 247, 250 (Minn. 2001). Product liability cases routinely hold that a product manufacturer, who knows of a dangerous condition but defers correction by engaging in a cost-benefit analysis, balancing

human lives against corporate profits, has demonstrated such "callous indifference to public safety" as to be subject to punitive damages. *See, e.g., Grimshaw v. Ford Motor Co.,* 119 Cal.App.3d 757, 174 Cal.Rptr. 348, 384 (1981) ("There was evidence that Ford could have corrected the hazardous design defects at minimal cost but decided to defer correction of the shortcomings by engaging in a cost-benefit analysis balancing human lives and limbs against corporate profits. Ford's institutional mentality was shown to be one of callous indifference to public safety."); *Hodder v. Goodyear Tire & Rubber Co.,* 426 N.W.2d 826, 835-36 (Minn.1988) (concluding that Goodyear's inadequate distribution of warnings about the danger of exploding rims, based on a corporate policy to restrict advertising dollars for projects that are not promoting product sales, was "willful indifference to the safety of others."); *Gryc v. Dayton-Hudson Corp.,* 297 N.W.2d 727 (Minn.1980) (upholding a punitive damages award against a manufacturer who continued, for profit reasons, to supply flammable nightwear when nonflammable material was available).

While many women have come forward and reported significant injuries resulting from this product, there are likely still numerous women who may suffer complications down the road, or who have not yet associated their complications with the product. Plaintiffs' post implant evidence is relevant to show culpability of Mentor. While a jury may not award punitive damages against a defendant to punish the defendant for harm to non-parties, a jury may consider whether the defendant's conduct risks harm to others in determining reprehensibility, so long as the trial court takes reasonable steps to ensure that the jury will not confuse the two concepts. *Philip Morris v. Williams*, 549 U.S. 346, 357 (2007).

Accordingly, such post-sale evidence is relevant in accordance with Fed. R. Evid. 401, 402 and 403.

CONCLUSION

Despite Mentor's contentions, post-implant evidence offered by Plaintiffs is relevant and admissible for multiple purposes.

Respectfully Submitted,

/s/ Richard N. Laminack
Richard N. Lamianck (SBOT 11850350)
Thomas W. Pirtle (SBOT 16038610)
Buffy K. Martines (SBOT 24030311)
Laminack, Pirtle & Martines, L.L.P.
5020 Montrose, 9th Floor
Houston, Texas 77006
Telephone: 713-292-2750
Facsimile: 713-292-2755

COUNSEL FOR PLAINTIFFS IRENE MOREY

CERTIFICATE OF SERVICE

I hereby certify that on April 26, 2013, a true and correct copy of the foregoing document and attached Exhibits were served, via the Court's electronic filing system, to all counsel of record.

/s/ Richard N. Laminack
Richard N. Laminack